REMARKS

In the Office action dated December 15th, 2004, the Examiner rejected claims 1, 6-7, 18-20 pursuant to 35 U.S.C. §102(b) as anticipated by *Siepser*, U.S. #5,203,865. The Examiner further rejected claims 8-14 pursuant to 35 U.S.C. §103(a) as obvious in light of *Siepser* and Claims 2-5 and 15-17 pursuant to 35 U.S.C. §103(a) as obvious in light of *Siepser* in view of *Ross, et al.*, U.S. #6,663,644.

Applicant has amended independent claims 1, 15, & 18 and dependent claims 13, 19, & 20 and believes the aforesaid together with the amended independent claims complies with the requirements of 35 U.S.C. §102(b) & §103(a). Applicant respectfully traverses the Examiner's rejection of the claims. Applicant further states that no new matter has been added to the present art Application.

Regarding the aforesaid §102(b) rejection of Applicant's claim 1 and the corresponding dependent claims 6 & 7, *Siepser* describes in the figures 5 & 6 referenced, a form of a prior art microvitreoretinal (MVR) blade. The radial optic neurotomy procedure is relatively new and requires an instrument distinct from an MVR blade in order to ensure surgical safety. That is, during the radial optic neurotomy procedure the greatest potential complication is hemorrhage. That is, a conventional prior art MVR blade as described in *Siepser* introduces a significant risk during the radial optic neurotomy procedure as the sharp nasal edges may cause an inadvertent disruption or cutting of the central retinal vessels or other complications. The present art invention allows atraumatic passage of the device alongside the central retinal artery and central retinal vein without the prior art risk of hemorrhage.

Siepser specifically describes in Column 4, Lines 60 - 68; Column 5, Lines 1 - 2:

> "Tip 68 is also shown in FIG. 5 as including side portions 72 and 74 which are **substantially symmetrical** about central axis 70. **Each of side portions 72 and 74 are shown to include a cutting edge 76 and 78**, which cutting edges are oriented at an angle with respect to central axis 70. Side portions 72 and 74 are also shown to include a tapered surface 80 and 82, respectively, which tapered surfaces extend away from cutting edges 76 and 78. **Side portions** 72 and 74 are further shown to include **side edges** 84 and 86, which **side edges are generally rounded**." (emphasis added)

Siepser specifically defines both of his legs of his "V" shaped tip, **76** & **78** as cutting edges. Nowhere does *Siepser* even suggest that one of edges **76** & **78** is or could be dulled for performance of a radial optic neurotomy procedure. *Siepser* specifically discloses a tapered surface **82** which forms said cutting edges, **76**, **78** and makes no mention of a dulled edge. (Note: tapered surface **80** cannot be found on Figs. 5 or 6 of *Siepser*.) *Siepser* states that his side portions **72**, **74** are "generally rounded" but these side portions are positioned near Applicant's transitional taper and not near any of the cutting edges.

Applicant's presently amended Claim 1 specifically places the cutting edge on one leg of the "V" and the dulled edge on the rotationally opposite leg of the "V", for use in the radial optic neurotomy procedure. By definition, a "V" shape has two legs and said legs are at the outermost portion of said "V". That is, the legs are not placed within the "V" shape but are on the edge. *Siepser*'s "tapered surface" **82**, referred to by the Examiner as "a dulled edge" at the tapered surface, is not at the legs of the "V" shape but instead is interior or within the "V" shape. Also, a tapered surface is not a mechanically equivalent element to a dulled edge as understood within the mechanical arts, even if it was placed at the "V" shape leg.

Regarding the aforesaid §102(b) rejection of Applicant's method claims 18 - 20, *Siepser* again describes in the figures 5 & 6 referenced, a form of a conventional prior art microvitreoretinal (MVR) blade. Said MVR blade is incompatible with the method of performing a radial optic neurotomy surgical procedure by atraumatically passing the tip alongside a central retinal artery or a central retinal vein. *Siepser*'s art of his Figs. 5 & 6 would easily cut said artery or vein with the two sharpened edges, cause hemorrhage, and result in blindness. The retinal veins and arteries are so delicate that they cannot be touched by a sharp edge without risk of hemorrhage. Furthermore, *Siepser* specifically places an angle of between 30 and 60 degrees between the shaft and blade which is incompatible with the radial optic neurotomy procedure. (Col. 5, Lines 20 - 24) The radial optic neurotomy procedure requires that the blade must be pushed substantially straight with said shaft; this is not possible with the art of *Siepser*. The aforesaid amended apparatus and method claims place the distal point substantially near the central axis of the shaft as described within Applicant's specification. This limitation is not found in *Siepser*.

Under 35 U.S.C. §102, anticipation requires that each and every element of the claimed invention be disclosed in the prior art. In addition, the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. U.S. International Trade Commission*, 1 USPQ 2d 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987). *Siepser* is silent about a dulled edge rotationally opposite from a sharpened edge and further does not disclose substantial alignment of the distal point with the shaft central axis. Failure of *Siepser* to place any one of the aforesaid does not satisfy the disclosure requirements of *Akzo N.V.*

Further relating to *Siepser*, invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). The prior art reference of *Siepser* does not disclose the aforesaid unique features, function, or result of Applicant. The aforesaid is further reinforced in *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 USPQ 2d 1481, 1490 (Fed. Cir. 1997) as stated, "for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art." *Motorola, Inc.* further states, "although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there." As aforesaid, each and every unique aforedescribed elements of Applicant is not

found in *Siepser*.

Regarding the rejected claims 8 - 14 pursuant to 35 U.S.C. §103(a) as obvious relative to *Siepser*, Applicant's present amendments and aforesaid remarks apply to the rejected dependent claims as relating to obviousness. None of the references cited, either individually or collectively, under 35 U.S.C. §103(a) have all of the elements of the amended independent claims presented herein, nor do they provide a motivation, suggestion, or teaching of the desirability of making the specific combination that was made by Applicant.

Regarding the Examiner's statements that "a mere change in size of a component" would have been obvious is well established and accepted within the law. Nevertheless, the present art apparatus and method claims specifically describe an instrument having distinct features relative to the prior art with a distinct method of use. That is, *Siepser* discloses two sharpened edges with a shaft handle which is between 30 and 60 degrees relative to the blade. Applicant discloses only one sharpened edge, a dulled edge substantially rotationally opposite said sharpened edge, and further places the distal point substantially near the central axis of the device as a whole. Even if through some contortion *Siepser* could be used for the radial optic neurotomy procedure, *Siepser* introduces hemorrhage complexities which are unacceptable. The amendments to the base independent claims therefore are verily believed to obviate the §103 *Siepser* rejection.

Regarding the rejected claims 2 - 5 and 15 -17 pursuant to 35 U.S.C. §103(a) as obvious relative to *Siepser*, in view of *Ross, et al.*, U.S. #6,663,644, Applicant's present amendments and aforesaid remarks apply to the rejected independent and dependent claims as relating to obviousness. Regarding the reference to Fig. 9 and Col. 8, Lines 61 - 63 and callouts #24 and #3 of *Ross, et al.*, Applicant has found the *Ross, et al.* patent to have only six (6) columns, no callout #3, and callout #24 to reference only a "gear assembly" in Col. 3, Lines 8 - 9 and not a depth gauge line. If the Examiner was referencing another patent, Applicant respectfully requests notification of said patent number and an opportunity prior to a final office action to review and respond to the prior art.

Fig. 9 of *Ross, et al.* is described in Col. 3, Lines 66 - 67 and Col. 4, Lines 1 - 8. It specifically states:

> "FIGS. 8, 9 and 10 show yet another embodiment of a blade assembly 10". The blade holder 36" of the assembly 10" has a pair of clips 60 that secure the holder 36" to the blade 38" within blade notches 48". The clips 60 secure the holder 36" to the blade 38" with frictional forces. With this embodiment the blade holder 36" can move relative to the blade 38" during installation into the microkeratome 12. The relative movement provides a mechanical float feature that compensates for tolerances in the cutting head assembly 18, particularly the cavity 42 of the microkeratome."

Nowhere does *Ross, et al.* describe a depth gauge line on the microkeratome. In fact the microkeratome described in *Ross, et al.* is utilized for creation of a lamella in the cornea prior to laser "LASIK" treatment of the cornea. The art of *Ross, et al.* is not and was never intended for retinal surgery. The two types of surgery are distinct and performed by different types of surgeons.

Although *Ross, et al.* does describe "blade notches 48"", he utilizes said notches to mechanically secure the holder to the blade38" and not as a visual monitoring reference of depth of penetration of said blade. Due to the nature of retinal surgery mechanical depth control of blade insertion depth is not possible. Instead, depth must be controlled by the surgeon via visual reference through the microscope with which he or she is working. That is, since the incision through the eye is so small during retinal surgery, attempts to place mechanical depth controllers on the present art would necessitate larger incisions within the eye which are undesirable and may result in greater trauma, loss of interocular pressure, and astigmatism during and after the healing process.

Regarding the aforesaid §103(a) rejections, the Federal Circuit now uses the suggestion test to assess obviousness rejections. In the case of *In re Kotzab*, 55 USPQ2d 1313 (Fed Cir. 2000), the Federal Circuit stated that "to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." (the term "*specific*" is emphasized) The cited *Ross, et al.* reference, does not provide a motivation, suggestion, or teaching of the desirability of providing the visually monitored depth gauge of the Applicant. This is especially true since a microkeratome as described in *Ross, et al.* could not utilize a visual reference for the precise corneal slicing required prior to the LASIK procedure. The aforesaid is further reinforced in *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 56 USPQ 2d 1456, 1459 (Fed. Cir. 2000) citing *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ 2d 1225, 1232 (Fed. Cir. 1998) which states as relating to obviousness, "the first requirement is that a showing of a suggestion, teaching, or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding."".

The aforesaid motivating suggestion must also be explicit. *Winner International Royalty Corp. v. Wang* 48 USPQ2d 1139, (D.C.D.C. 1998). The fact that prior art "may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 922 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992). Again, as aforesaid and without suggestion by the Examiner, *Ross, et al.* does not provide a motivation, suggestion, or teaching of the desirability of providing visual depth control for the radial optic neurotomy procedure as does the Applicant.

In view of the foregoing, the independent claims along with their corresponding dependent claims are herewith submitted as patentable. Accordingly, favorable reconsideration and allowance of this application is requested.

Respectfully submitted,

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CERTIFICATE OF MAILING

I certify that the foregoing **AMENDMENT A** is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Commissioner of Patents, Mail Stop Non-Fee Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on March 14, 2005.

Kevin L. Klug